

medicament until the desired result is achieved, note that the containers/blisters may have different amounts of medicament (col. 42 lines 6-50) these differences being predetermined when the blisters are filled, note the abstract for the use of a dry powder).

The abstract describes enhancing absorption by instructing the patient to inhale maximally and thereafter exhale maximally. The abstract also describes an electronic sensor that measures air flow and volume when the patient is inhaling in order to control the precise point in time of drug release. The sensor can also assist the patient in the inhale-exhale maneuver, which is later called "coaching." The abstract says nothing about repeated deliveries of medicament.

Col. 42 describes "indices" that are included with the drug containers. The indices may be electronic (col. 42, lines 6-7) and provide information to the patient (col. 42, line 14). The indices "can be designed for any desired purpose but in general provide[] specific information relating to the day an/or time which the drug within a container should be administered" (col. 42, lines 14-17). The indices can also provide information on the "amount of insulin dispensed from each container which might be particularly useful if the containers included different amounts of insulin." (col. 42, lines 26-28). The indices "could have new information [e.g., time of delivery] recorded onto them which information could be placed there by the drug dispensing device." (col. 42, lines 29-35).

While the passage at col. 42 indicates that there could be different amounts of medicament in different containers, there is no indication that the different containers in the same strip should have different amounts, or that a patient should take drugs from two separate containers to get a variable dose.

Gonda also describes setting the piston of the drug release device to release all or a percentage of the contents of a container at col. 23, lines 26-30, and moving from one container to another in a dosing event involving several inhalations at col. 31, lines 47-52. There still, however, is no teaching or suggestion of taking drugs from containers with different doses in order to get a variable dose, as required by claim 1.

The cited references, taken alone or in combination, do not disclose or suggest a single use inhaler with a subsidiary dose that is less than the first dose to permit a user to choose

whether or not to use the subsidiary dose with the primary dose to provide a variable dose as required by claim 1, and claim 1 is patentable under 35 USC 103(a).

Gottenauer U.S. Patent No. 5,881,719 is cited as the primary reference against independent claims 9 and 10 for disclosure of a device with first and second doses and release means, and Gonda is combined with the primary reference in the same manner as in the rejection against claim 1 for disclosure of "predetermined fractions of doses of one blister relative to another," citing the abstract and col. 42. As noted above with respect to claim 1, there is no teaching or suggestion in Gonda of taking drugs from containers with different doses in order to get a variable dose, as required by claims 9 and 10, and the cited references, taken alone or in combination, do not disclose or suggest a single use inhaler with a subsidiary dose that is less than the first dose to permit a user to choose whether or not to use the subsidiary dose with the primary dose to provide a variable dose. Claims 9 and 10 thus are patentable under 35 USC 103(a).

The remaining claims depend on the independent claims and are allowable with them.

The claims have also been rejected for obviousness type double patenting on the basis of Kallstrand U.S. Patent No. 5,533,505 considered in view of Gonda U.S. Patent No. 5,743,250. Kallstrand only shows, and claims, a device with a single compartment. The claims herein require, in addition, a further compartment with a subsidiary dose that is less than the first dose to permit a user to choose whether or not to use the subsidiary dose with the primary dose to provide a variable dose. This is nowhere suggested by the '505 patent. This feature also is nowhere disclosed or suggested in Gonda, as noted above, and the rejection should be withdrawn. This is more than the duplication of a known part for a known purpose, because it permits the user to make a decision and select a larger dose.

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Applicant asks that all claims be allowed. Enclosed is \$400 check for the Petition for Extension of Time fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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